

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

|                                  |   |                          |
|----------------------------------|---|--------------------------|
| In re Application of:            | ) |                          |
|                                  | ) |                          |
| Chikamasa Yamashita et al.       | ) | Group Art Unit: 1616     |
|                                  | ) |                          |
| Application No.: 10/538,837      | ) | Examiner: James Alstrum- |
|                                  | ) | Acevedo                  |
| Filed: June 13, 2005             | ) |                          |
|                                  | ) |                          |
| For: NOVEL DRY POWDER INHALATION | ) |                          |
| SYSTEM FOR TRANSPULMONARY        | ) | Confirmation No.: 5653   |
| ADMINISTRATION                   | ) |                          |

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**DECLARATION UNDER 37 C.F.R. § 1.132**

We, Chikamasa Yamashita, Akitsuna Akagi, and Yuichiro Fukunaga, hereby  
declare that:

- (1) We are the inventors named in the present application.
- (2) We are each named inventors in U.S. Patent App. No. 10/170,339, which  
corresponds to U.S. Patent App. Pub. No. 2003/0101995.
- (3) We, along with Shigeru Ibaragi, jointly invented the "dry powder inhalation  
system" as claimed in U.S. Patent App. No. 10/170,339.
- (4) We determined that a liquid composition containing pharmacologically active  
substance, to be filled as a liquid into vessels, can be prepared as a freeze-dried  
composition.

(5) We determined that the preparation described in (4), above, is possible where the freeze-dried composition is capable of being made into fine particles suitable for transpulmonary administration through a predetermined air impact.

(6) An aspect of the "freeze-dried composition for transpulmonary administration" of the present invention is that this freeze-dried composition is prepared by freeze-drying a liquid composition containing ingredients in a non-dissolved form.

(7) We determined that the ingredients, in particular the pharmaceutically active substance as an active ingredient, in the liquid composition may be either partially dissolved within the liquid composition or not dissolved within the liquid composition. We made this determination independently from the contributions of Shigeru Ibaragi.

We declare further that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: April 16, 2009

By: Chikamasa Yamashita  
Chikamasa Yamashita

Date: April 16, 2009

By: Akitsuna Akagi  
Akitsuna Akagi

Date: April 16, 2009

By: Yuichiro Fukunaga  
Yuichiro Fukunaga